

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**COLUMBIA UNIVERSITY'S RESPONSE TO PLAINTIFFS' REPORT TO THE
COURT PURSUANT TO ORDER DATED MAY 17, 2005**

In its Order dated May 17, 2005, the Court requested the parties to submit reports in which they responded to a series of questions posed by the Court. The Court further requested the parties to file responses to the reports by June 20, 2005. Below is Columbia's response to plaintiffs' reports. Many of the points covered by plaintiffs in their reports have already been comprehensively briefed by the parties. Columbia has endeavored to avoid belaboring points that it has made in previous submissions to the Court and, instead, to focus on new issues and arguments, to the limited extent they are raised in plaintiffs' reports.

I. *Biogen, Inc., Genzyme Corp., and Abbott Bioresearch Center, Inc. v. Columbia University*, Case No. 03cv11329 MLW

A. The Court Should Dismiss Count I

Count I of *Biogen I*—the first suit involving Biogen Idec MA, Inc. and Genzyme Corporation—seeks a declaration that the '275 patent is invalid and unenforceable and that Biogen and Genzyme therefore owe no royalties under their license agreements with Columbia. This Court's November 5 Order makes clear that it will dismiss all declaratory judgment claims involving the validity and enforceability of the '275 patent either because there is no longer an actual case or controversy, or because the interests of justice do not warrant the Court's

exercising its discretion to retain jurisdiction. Count I is thus plainly covered by the November 5 Order.

Biogen and Genzyme argue that an actual controversy exists as to whether Columbia improperly terminated their license agreements prior to filing the covenant not to sue and is therefore liable for breach of contract. This allegation is not contained in Count I of *Biogen I*. Nor has Biogen or Genzyme ever sought leave to amend Count I to include any such allegation. The only place where Biogen and Genzyme make this allegation is in a *breach of contract claim* pled in Count II(A) of their second filed action (*Biogen II*). Whether Count II(A) should be allowed to proceed will be decided when the Court rules on Columbia's pending motions to dismiss in *Biogen II*. In any event, because this allegation is not contained in *Biogen I*, and because Columbia's covenant not to sue eliminates any justiciable controversy with respect to any declaratory relief claim concerning the validity or enforceability of the '275 patent, the Court should dismiss Count I along with the rest of *Biogen I*.

Given that Biogen and Genzyme have asserted their breach of contract claim in *Biogen II*, why do they continue to insist that the Court retain jurisdiction over *Biogen I*? The answer is that Biogen and Genzyme are desperate to avoid a procedural morass of their own creation. In a telephonic hearing conducted on September 9, 2004, counsel for Biogen and Genzyme announced that his clients desired to assert additional claims against Columbia relating to patent misuse and license termination. Ex. A (Tr. at 20:1-12). At that point, plaintiffs should have moved to amend their complaint—just as the Court directed during the telephonic hearing. *Id.* (Tr. at 20:13-16). They chose not to do so. Unwilling to let this Court decide whether amendment was appropriate, plaintiffs instead filed *Biogen II*. On October 1, 2004, Columbia

moved to dismiss *Biogen II* on the ground that it represented a transparent effort to circumvent Federal Rule of Civil Procedure 15.

If plaintiffs lose that motion to dismiss—as they should, given that *Biogen II* was filed in direct contravention of Rule 15, as well as the Court’s own directive during the September 9 telephonic hearing—their only remaining option will be to seek leave to amend their pleading in *Biogen I* (which has already been amended once before). As plaintiffs undoubtedly know, such a motion is unlikely to succeed. Courts look with disfavor on motions that seek to add preexisting claims once dispositive rulings have been made. *See, e.g., LaRocca v. Borden, Inc.*, 276 F.3d 22, 32 (1st Cir. 2002) (affirming district court’s denial of leave to amend, court explained that plaintiffs had unduly delayed by moving to amend “after the court had issued an all-but-dispositive ruling on cross-motions for summary judgment”); *Cobb v. Supreme Judicial Court of Mass.*, 334 F. Supp. 2d 60, 62 (D. Mass. 2004) (denying motion for leave to amend when, after hearing on defendants’ motion to dismiss, plaintiff moved to amend in “an obvious effort . . . to avert the dismissal of the case that the court stated was likely to be forthcoming”).

Biogen and Genzyme’s failure to seek leave to assert this preexisting claim will make it quite difficult for them to do so now, particularly given that their license agreements were terminated more than one year ago.¹ Thus, knowing that the Court likely will dismiss their claims in *Biogen II* as an improper attempt to circumvent Rule 15, and knowing that it will be very difficult to secure leave to amend in *Biogen I* after the granting of a dispositive motion, Biogen and Genzyme have resorted to mischaracterizing the allegations in *Biogen I* in an ill-

¹ Biogen’s license agreement was terminated effective April 8, 2004. Genzyme’s license agreement was terminated effective May 8, 2004. Both license agreements were subsequently reinstated as of the date on which they were initially terminated as a consequence of Columbia’s covenant not to sue.

conceived effort to preserve their purported wrongful termination claim. The Court should not countenance this procedural gamesmanship.

In a final attempt to resuscitate *Biogen I*, plaintiffs argue that they can cure any “technical deficiency” in Count I via an amendment pursuant to 28 U.S.C. § 1653. Response at 5 n.3. Plaintiffs are wrong. Section 1653 “addresses only incorrect statements about jurisdiction that actually exists, and not defects in the jurisdictional facts themselves.” *Newman-Green, Inc. v. Alfonzo-Larrain*, 490 U.S. 826, 831 (1989). Therefore, “section 1653, even liberally construed, does not allow a plaintiff to amend its complaint to substitute a new cause of action over which there is subject-matter jurisdiction for one in which there is not.” *Advani Enters., Inc. v. Underwriters at Lloyds*, 140 F.3d 157, 161 (2d Cir. 1998).

B. Consolidation of *Biogen I* and *Biogen II* Is Not Appropriate

There is no subject matter jurisdiction over any of the declaratory relief claims asserted in *Biogen I*. Accordingly, because *Biogen I* will be dismissed in its entirety, it cannot be consolidated with *Biogen II*.

Biogen and Genzyme chastise Columbia for rejecting their offer to stipulate to the dismissal of all claims in *Biogen I* in return for Columbia’s agreement that they may proceed “on the merits” in *Biogen II*. Response at 6. It is hard to understand why Biogen and Genzyme believe that Columbia would find this offer attractive. As to *Biogen I*, the Court’s November 5 Order already requires the dismissal of all claims in that action. As to *Biogen II*, Columbia has two pending motions to dismiss, both of which are meritorious. Plaintiffs’ offer certainly has upside for them—but none for Columbia.

In addition, Biogen and Genzyme accuse Columbia of taking the “contradictory positions” that *Biogen I* should be dismissed while at the same time maintaining that plaintiffs should have sought leave to amend *Biogen I* instead of filing *Biogen II*. *Id.* There is nothing

contradictory about Columbia's positions. Rather, plaintiffs' argument is based on the false assumption that they are *entitled* to pursue their new claims *somewhere*—either in *Biogen I* or *Biogen II*. Unfortunately, plaintiffs have overplayed their procedural hand. Instead of complying with Rule 15, they filed a second action alleging claims that they should have sought leave to assert in *Biogen I*. As a result, *Biogen II* must be dismissed as an improper end-run around Rule 15. And now that the Court has already ruled on Columbia's motion to dismiss in *Biogen I*—requiring the complete dismissal of that case—it is too late for plaintiffs to make a motion to amend that they could have filed months and months ago. Biogen and Genzyme may find themselves lodged between the proverbial “rock and a hard place”—but that's only because they put themselves there.²

C. The Court Should Not Stay *Biogen I* and *Biogen II*

There is no reason for the Court to stay *Biogen I* or *Biogen II*. Given that all claims in *Biogen I* are covered by Columbia's covenant not to sue and thus will be dismissed by the Court for lack of subject matter jurisdiction, there is nothing for the Court to stay in that case.

Moreover, because plaintiffs' claims in *Biogen II*—abuse of process, breach of contract, and unfair competition—do not turn on the outcome of the reexamination and reissue proceedings in

² Nor would Biogen and Genzyme be entitled to file a second action if the Court were to deny leave to amend in *Biogen I*. Courts in this district and others have prevented parties from bringing claims in a new action after a motion to amend to add those claims was denied based on undue delay and prejudice. *See Trimless-Flashless Design, Inc. v. Augat, Inc.*, No. 02-11375-RWZ, 2002 WL 31640533, at *2 (D. Mass. Nov. 21, 2002) (granting motion to dismiss later-filed action after leave to amend denied in previous action based on “prejudice and injustice,” court explained that plaintiff “had numerous opportunities to add” its claim “as it became clear that the issue was central to the case” and would not be allowed “to belatedly repair [its] error with this lawsuit”); *United States v. McGann*, 951 F. Supp. 372, 379 (E.D.N.Y. 1997) (after government's motion to amend was denied based on undue delay and prejudice and government filed new complaint with same claims, court dismissed new complaint under *res judicata* principles since “the government is attempting an end run around the denial of its motion to amend its complaint by filing a new one, or as it is occasionally put, attempting to accomplish indirectly what it could not accomplish directly”).

the Patent and Trademark Office, there is no reason for the Court to await a decision on the fate of the '275 patent. Biogen and Genzyme have requested a stay for no other reason than to avoid the dismissal of *Biogen I* and *Biogen II*. Judicial economy favors a prompt ruling on these dispositive motions—not an indefinite deferral.

D. Because There Is No Subject Matter Jurisdiction, The Court Cannot Retain Jurisdiction Over *Biogen I*

Biogen and Genzyme propose that the Court retain subject matter jurisdiction for the supposed purpose of enforcing Columbia's covenant not to sue, even though the Court has determined that it lacks subject matter jurisdiction over all declaratory relief claims involving the validity or enforceability of the '275 patent. Biogen and Genzyme provide no authority supporting this proposal, as there is none.

On the other hand, Columbia has found case law that is contrary to plaintiffs' position. In *Inline Connection Corp. v. Atlantech Online, Inc.*, 85 Fed. Appx. 767 (Fed. Cir. 2004) (unpublished), Inline filed a motion to dismiss that included a covenant not to sue Atlantech for infringement of three patents. Atlantech objected to certain language in the motion to dismiss, which described the covenant as "personal" and "non-transferable," on the ground that it was an improper attempt "to alter the res judicata or claim preclusive effect of the dismissal." *Id.* at 768. Instead of simply granting the motion to dismiss, the district court entered a permanent injunction, at Atlantech's request, specifying whom Inline could sue in the future for patent infringement in light of the covenant not to sue. *Id.* In so doing, the district court effectively retained jurisdiction to enforce its permanent injunction construing and enforcing the covenant not to sue. On appeal, the Federal Circuit dissolved the injunction, explaining that the covenant "divested the district court of subject matter jurisdiction over the case. *The district court did not have jurisdiction to enter an injunction and should have simply dismissed the complaint with*

prejudice . . . as moot.” Id. at 769 (emphasis added). Although *Inline Connection* is an unpublished Federal Circuit decision, it was recently cited by Judge O’Toole of this District in a decision dismissing patent declaratory judgment claims for lack of subject matter jurisdiction because of a covenant not to sue. *Vision Biosystems (USA) Trading Inc. v. Ventana Medical Sys., Inc.*, No. 03-10391-GAO, 2004 WL 2387284, at *11 n.2 (D. Mass. Sept. 30, 2004). Here, because Columbia’s covenant not to sue divested the Court of subject matter jurisdiction, the Court should simply dismiss plaintiffs’ claims.

No other party in this multidistrict litigation has proposed that the Court’s order of dismissal also purport to retain jurisdiction to enforce the covenant not to sue. Given the lack of support for plaintiffs’ position, this is not surprising. Indeed, the only cases that plaintiffs cite in their memorandum to support the retention of jurisdiction are inapposite.

Plaintiffs rely upon language in *ATMI, Inc. v. Innovative Eng’g Solutions, Inc.*, No. C 01-1729 SI, 2002 WL 826794 (N.D. Cal. Apr. 29, 2002), for the proposition that a covenant not to sue is “binding upon” the defendant. *Id.* at *2. That proposition is certainly true. But nothing in this case suggests that a district court can or should retain jurisdiction over an action that, in light of a covenant not to sue, must be dismissed for lack of subject matter jurisdiction. Indeed, the court in *ATMI* simply dismissed the plaintiff’s patent declaratory judgment claims based on the defendant’s covenant not to sue, without retaining jurisdiction over the case for any purpose.

Nor is *Highway Equip. Co. v. FECO, Ltd.*, No. C03-0076, 2005 WL 936469 (N.D. Iowa Apr. 22, 2005), of any help to plaintiffs. In that case, the court retained jurisdiction to decide the defendant’s claim for attorney’s fees after granting the plaintiff’s motion to dismiss its declaratory relief claims based on a covenant not to sue. *Id.* at *2. This result is hardly surprising, given that there is considerable authority supporting the proposition that a district

court retains discretionary jurisdiction after granting a motion to dismiss for the limited purpose of entertaining a request for attorney's fees.³ On the other hand, there is absolutely no authority supporting the notion that a district court can indefinitely retain subject matter jurisdiction over a case that it has dismissed for lack of subject matter jurisdiction. The district court in *Highway Equip.* entered no such order—nor has any other court, to Columbia's knowledge. Columbia respectfully requests that the Court reject this nonsensical notion.⁴

II. *Genentech, Inc. v. Columbia University*, Case No. 04cv11546 MLW, previously Case No. 04cv1910 VRW (N.D. Cal.)

A. The Court Should Suggest Remand of Genentech's Fifth Claim

Genentech's sole remaining claim is for breach of contract based on Columbia's termination of Genentech's license agreement on account of its failure to allow an audit. No other party in the multidistrict litigation has asserted a breach of contract claim relating to termination on these grounds. In fact, Genentech's attempt to establish commonality with other plaintiffs' claims relies solely on Wyeth's *proposed* breach of contract claim, which Wyeth has sought leave to assert. [Docket No. 178, Ex. A at ¶ 142.] Of course, Genentech neglects to point out that Wyeth's breach of contract claim is not based on termination for failure to allow an

³ See, e.g., *Cambridge Prods., Ltd. v. Penn Nutrients, Inc.*, 962 F.2d 1048, 1050-51 (Fed. Cir. 1992) (affirming district court's denial of attorney's fees, which were considered following an order granting plaintiffs' motion for voluntary dismissal of its patent infringement action); *Bioxy, Inc. v. Birko Corp.*, 935 F. Supp. 737, 744 (E.D.N.C. 1996) (considering defendant's claim for attorney's fees after granting plaintiff's motion to voluntarily dismiss its infringement action); *Huey Co. v. Alvin and Co., Inc.*, 224 U.S.P.Q. 1071, 1072 (D. Conn. 1984) (explaining that "the court retains jurisdiction to determine whether attorney fees should be awarded under 35 U.S.C. § 285" even though the disclaimer of the patent mooted the infringement action).

⁴ Biogen and Genzyme complain that Columbia's proposed order of dismissal does not specify that dismissal is without prejudice. Given that Federal Rule of Civil Procedure 41(b) expressly provides that dismissal for lack of subject matter jurisdiction is not an adjudication on the merits, it is hardly necessary to add this redundant language—and no other plaintiff has requested it. Columbia has no objection, however, if the Court prefers to include this language in the order of dismissal.

audit, but for termination based on failure to pay all annual fees. The two grounds are entirely different.

Genentech's one remaining claim is specific and unique. It has nothing to do with the common issue that warranted consolidation in the first place—the validity and enforceability of the '275 patent. The Judicial Panel on Multidistrict Litigation (“JPML”) ordered consolidation—over Genentech's strident objection—because “[a]ll actions can . . . be expected to share factual and legal questions with respect to the '275 patent concerning patent validity and related questions such as double patenting, prosecution laches, and inequitable conduct.” *In re Columbia University Patent Litig.*, 313 F. Supp. 2d 1383, 1385 (J.P.M.L. 2004). Those common factual and legal questions no longer exist.⁵

Perhaps recognizing the absence of common links between the cases in the multidistrict litigation, Genentech contends that its Fifth Claim, which does not in any way relate to the validity and enforceability of the '275 patent, should not be remanded because there might be litigation in the future regarding any potential reissue of the '275 patent. As the Court has previously recognized, the chance of a future dispute between the parties regarding the '275 patent is highly speculative. November 5 Order at 25, 28. In any event, any such potential dispute provides no reason for the Court to retain jurisdiction over a contract claim that is entirely unrelated to the '275 patent.

⁵ Decisions from the district courts and the JPML consistently hold that when only case-specific issues remain, remand is appropriate. *See In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 169 F.R.D. 632, 638 (N.D. Ill. 1996) (explaining that multidistrict litigation is intended to deal with “common questions of fact” and “is not the appropriate mechanism for the conduct of case-specific discovery”); *In re Air Crash Disaster At Tenerife, Canary Islands on Mar. 27, 1977*, 461 F. Supp. 671, 673 (J.P.M.L. 1978) (remanding particular action, court explained that “the remaining discovery . . . concerns the issue of damages, and all other remaining pretrial proceedings . . . are primarily, if not entirely, unique [to that action]”).

III. *Wyeth and Genetics Institute LLC v. Columbia University*, Case No. 03cv11570 MLW

Wyeth and Genetics Institute's Fourth, Fifth, and Sixth claims seek declaratory relief—nothing more, nothing less. These claims relate to the '275 patent and pending patent applications. Columbia committed in writing not to seek royalties on pending patent applications and covenanted not to sue Wyeth and Genetics Institute on the '275 patent. This Court has already determined that these developments eliminate the existence of subject matter jurisdiction over plaintiffs' declaratory relief claims. Accordingly, these claims must be dismissed pursuant to the Court's November 5 Order.

Wyeth and Genetics Institute argue that these declaratory relief claims are actually “direct actions for past wrongs committed by Columbia . . . relat[ing] to Wyeth's right to the return of fees and royalty payments totaling \$2,273,465.33” that Wyeth alleges it mistakenly paid to Columbia for ReFacto, one of Wyeth's products. Status Report at 3. These declaratory relief claims contain no such allegations. Indeed, Wyeth and Genetics Institute recognize as much, given that they are currently seeking leave to amend their complaint to add entirely new allegations (which Columbia in no way concedes) that they “mistakenly paid Columbia a total of \$2,273,465.33 in royalties on ReFacto.” [Docket No. 178, Ex. A at ¶46.] Because plaintiffs' Fourth, Fifth, and Sixth claims contain no allegations relating to the return of any fees or royalties mistakenly paid on ReFacto, they are covered by the November 5 Order and must be dismissed by the Court.

IV. *Immunex Corp. and Amgen, Inc. v. Columbia University*, Case No. 04cv10740 MLW, previously Case No. 03cv4349 MRP (C.D. Cal.) (“Amgen”)**A. The Court Should Dismiss Amgen's First And Seventh Claims for Relief**

The First Claim of its Second Amended Complaint (“SAC”) is *expressly* predicated *solely* upon Columbia's demand for royalties on the basis of pending patent applications. SAC

¶¶ 58(b), 62. In the face of this incontrovertible language, Amgen now asserts that the First Claim was intended to cover an unrelated royalty dispute not over Columbia's pending patent applications, but Columbia's expired patents.

Amgen *never made this argument* in opposing Columbia's motion to dismiss. Indeed, Amgen never once argued that the First Claim applied to anything other than a dispute over royalty payments on pending patent applications, despite having ample opportunity and incentive to do so. And, in making this argument now, Amgen does not explain why it failed to raise this argument in a timely manner.

Instead, Amgen blithely asserts—without any legal authority—that the phrase “*inter alia*” in the First Claim should be read by the Court as sufficient to sweep within the legitimate ambit of this claim a completely unrelated royalty dispute having *nothing* to do with pending patent applications. Not only is this a tortured and meritless reading of the First Claim, it is a transparent effort by Amgen to transform the First Claim into a defense to Columbia's contract counterclaims—all of which are based solely upon the more than \$100 million in royalties and interest owed by Amgen to Columbia under Columbia's expired original Axel patents.

Had Amgen truly intended its First Claim to be as broad as it now contends, it could have drafted its claim appropriately, or at least raised this argument in opposition to Columbia's motion to dismiss, where the scope of this claim was squarely put into issue.⁶

B. Leave To Amend Should Be Denied

Amgen failed to disclose to this Court, when moving for leave to amend initially, that the Central District previously entered an order *precluding* Amgen from making any further

⁶ The same arguments apply with even more force, of course, to Amgen's Seventh Claim. Although Amgen at least opposed Columbia's motion to dismiss as to the First Claim (on grounds squarely rejected by this Court, and without once raising their argument *du jour*), Amgen was *completely silent* as to the Seventh Claim.

amendments to its pleadings. Incredibly, Amgen once again ignores that Central District order, even though Amgen is well aware of its importance and relevance.

Columbia has already addressed, in numerous earlier filings, all of Amgen's arguments regarding amendment, none of which is new, and will therefore not burden the Court with additional paper on this subject.

C. Consolidation Should Be Denied

With respect to consolidation, Amgen merely repeats, in its June 10, 2005 filing, the same arguments that it made in the reply brief it filed on February 11, 2005. While Columbia appreciates that Amgen has—in the face of controlling Supreme Court precedent against it—withdrawn its demand that the Amgen Affiliate action should be consolidated with the other MDL cases for trial, that concession simply does not resolve the consolidation issue.

Notably, Amgen has not to date addressed the fact that there is a pending motion to dismiss for lack of subject matter jurisdiction in the Amgen Affiliate action that will be dispositive of that entire action. It simply does not make sense, as a matter of logic or efficiency, for the Court to consolidate the Amgen Affiliate suit before first deciding whether there is anything left of that action to consolidate.

Moreover, Amgen's contention that the facts of the Amgen Affiliate suit overlap with the pending MDL suits must be viewed with skepticism, given that the Amgen Affiliates' claims exactly mirror the claims that this Court dismissed in November of 2004. Indeed, it is worth noting, as discussed above, that the sole remaining dispute between Columbia and Amgen is a contract dispute with respect to royalties owed under the original Axel patents (not the '275 patent). In light of this reality—and despite Amgen's reach to suggest that there are overlapping questions of law and fact between, on the one hand, the novel (and factually unsupported) defenses it raises to the contract claims on the original Axel patents and, on the other hand, the

declaratory judgment claims on the '275 patent—Amgen's motion to consolidate should be denied.

D. The Court Should Suggest Remand of Columbia's Counterclaims

What Columbia may have argued in seeking an MDL transfer is no more relevant to the question of whether the case is now ripe for remand than what Amgen argued in resisting that MDL transfer. The question for purposes of the remand analysis is whether the specific basis upon which the JPML made a decision to order transfer of the *Amgen* case to this Court continues to exist. Here, the express basis for transfer by the JPML was the existence of common questions of law and fact, and Amgen does not allege otherwise.

Instead, Amgen goes in search of common questions of law and fact on matters that were expressly *not* the basis of the JPML's transfer order. Amgen's case, however, presents unique issues that do not, in fact, overlap with the other MDL suits. Amgen is the only one of the plaintiffs that refused to pay royalties on products made before the expiration of the original Axel patents but sold after that time. As a result, Amgen is the only plaintiff that Columbia is suing for payment of past due royalties. Amgen owes Columbia well in excess of \$100 million, and the discovery that will take place with respect to this claim is unique to Amgen. Indeed, this will be true whether Amgen's First and Seventh Claims survive the motion to dismiss or not, since Amgen is now conveniently re-engineering these claims to be *defenses* to Columbia's counterclaims. For these and the other reasons discussed at length in Columbia's previous filings, the Amgen case is unique. With the common issues of fact and law pertaining to the '275 patent now removed from this case, the Court should suggest remand of this action to the transferor court.

Respectfully submitted,

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